

Claims

- 5     1. The use of a consumable film comprising triprolidine or a salt or hydrate thereof as active ingredient of an aid to waking refreshed after sleeping.
2. The use of a consumable film comprising triprolidine or a salt or hydrate thereof as active ingredient in the preparation of a composition for enabling an individual to  
10     wake refreshed after sleeping.
3. The use of a consumable film comprising triprolidine or a salt or hydrate thereof as active ingredient in the preparation of a medicament for enabling an individual to wake refreshed after sleeping.  
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4. The use of a consumable film comprising triprolidine or a salt or hydrate thereof in the preparation of a sleep aid which also enables an individual to wake refreshed after sleeping.
- 20     5. The use of a consumable film comprising triprolidine or a salt or hydrate thereof as active ingredient of a sleep aid which also enables an individual to wake refreshed after sleeping.
- 25     6. The use of a consumable film comprising triprolidine or a salt or hydrate thereof as active ingredient in the preparation of a medicament for the treatment or prevention of a sleep disorder which also enables an individual to wake refreshed after sleeping.
- 30     7. Use of a consumable film comprising triprolidine as active ingredient in the manufacture of a composition for the treatment of sleep disorders.
- 35     8. The use of a consumable film comprising triprolidine as active ingredient in the manufacture of a composition for inducing, prolonging and/or enhancing sleep and/or sleep quality.

- 5 9. A method for the treatment or prevention of grogginess, drowsiness or lethargy on waking from sleep in a mammal comprising the administration to the mammal in need thereof of a consumable film comprising a non-toxic effective dose of triprolidine or a salt or hydrate thereof prior to the desired sleeping time.
- 10 10. A method for enabling an individual to wake refreshed after sleeping comprising the administration to the individual in need thereof and prior to the desired sleeping time of a consumable film comprising a non-toxic effective dose of triprolidine or a salt or hydrate thereof.
- 15 11. A method for aiding an individual's sleep and for also enabling the individual to subsequently wake refreshed after sleeping comprising the administration to the individual in need thereof and prior to the desired sleeping time of a consumable film comprising a non-toxic effective dose of triprolidine or a salt or hydrate thereof.
- 20 12. A method of treating sleep of a person suffering from a sleep disorder, which method comprises administration of a consumable film comprising an effective dose of triprolidine as active ingredient to such a person.
- 25 13. A method for inducing, prolonging and/or enhancing sleep, which method comprises administration of a consumable film comprising an effective dose of triprolidine as active ingredient to a person desirous of achieving sleep.
- 30 14. A waking refreshed aid in the form of a consumable film comprising triprolidine or a salt or hydrate thereof as active ingredient in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time.
- 35 15. A pharmaceutical formulation for the treatment or prevention of grogginess, drowsiness or lethargy on waking after sleeping in the form of a consumable film comprising triprolidine or a salt or hydrate thereof as active ingredient in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time.

16. A pharmaceutical formulation for enabling an individual to wake more refreshed after sleeping, in the form of a consumable film comprising triprolidine or a salt or hydrate thereof as active ingredient in association with a pharmaceutically acceptable carrier therefor and instructions for administration thereof at or just before the desired sleeping time.
17. The use as claimed in any of claims 1-8, wherein the dose of triprolidine administered to the user prior to sleeptime is between 0.01mg and 20mg.
18. The use as claimed in any of claims 1-8, wherein the dose of triprolidine administered to the user before sleeptime is up to 20mg.
19. The method as claimed in any of claims 9-13, wherein the dose of active ingredient of triprolidine administered is between 0.01 and 20mg.
20. The method as claimed in any of claims 9-13 wherein the dose of active ingredient of triprolidine administered is up to 20mg.
21. The pharmaceutical formulation as claimed in any of claims 15 or 16, wherein the instructions for administration instruct a single dose of the active ingredient of triprolidine of up to 20mg prior to sleeptime.
22. The pharmaceutical formulation as claimed in any of claims 15 or 16, wherein the instructions for administration instruct a single dose of the active ingredient of triprolidine of between 0.01 and 20mg prior to sleeptime.
23. A waking refreshed aid as claimed in claim 14, wherein the instructions for administration instruct a single dose of the active ingredient of up to 20mg prior to sleeptime.
24. A waking refreshed aid as claimed in claim 14, wherein the instructions for administration instruct a single dose of the active ingredient of triprolidine of between 0.01 and 20mg prior to sleeptime.

25. A method as claimed in any of claims 9-13, 19 or 20, wherein the triprolidine is in the form of triprolidine hydrochloride.
26. A method as claimed in any of claims 9-13, 19, 20 or 25, wherein the person is suffering from a sleep disorder.
27. A method as claimed in any of claims 9-13, 19, 20 or 25, wherein the person is not suffering from a sleep disorder but is desirous of achieving a feeling of waking refreshed upon waking.
28. A method as claimed in any of claims 9-13, 19, 20 or 25-27 in which the active ingredient is administered between 1 minute and 2 hours prior to sleeptime.
29. Use as claimed in any of claims 1-8, 17 or 18, wherein the triprolidine is in the form of triprolidine hydrochloride.
30. Use as claimed in any one of Claims 1-8, 17, 18 or 29, wherein the composition is an edible film.
31. Use as claimed in any of claims 1-8, 17, 18, 29 or 30, wherein the active agent is in a form which is absorbable via the digestive tract.
32. The use as claimed in any one of Claims 29 to 31, which is free of ingredients intended or effective to sustain or prolong release of the active ingredient.
33. The uses of triprolidine as hereinbefore described and with reference to the examples.
34. The methods for the treatment of grogginess as hereinbefore described and with reference to the examples.
35. The films as hereinbefore described and with reference to the examples.
36. The pharmaceutical formulations as hereinbefore described and with reference to the examples.

37. The waking refreshed aids as hereinbefore described and with reference to the examples.

5 38. The method for enabling an individual to wake refreshed after sleeping as hereinbefore described and with reference to the examples.

39. A waking refreshed aid as hereinbefore described and with reference to the examples.

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40. A pharmaceutical formulation as hereinbefore described and with reference to the examples.

15 41. Use of triprolidine as active ingredient in the manufacture of a composition for the treatment of sleep disorders as hereinbefore described and with reference to the examples.

20 42. The use of triprolidine as active ingredient in the manufacture of a composition for inducing, prolonging and/or enhancing sleep as hereinbefore described and with reference to the examples.

25 43. A method of treating sleep of a person suffering from a sleep disorder, which method comprises administration of a consumable film comprising an effective dose of triprolidine as active ingredient to such a person as hereinbefore described and with reference to the examples.

30 44. A method for inducing, prolonging and/or enhancing sleep, which method comprises administration of a consumable film comprising an effective dose of triprolidine as active ingredient to a person desirous of achieving sleep as hereinbefore described and with reference to the examples.

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